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App. for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER 701039-52287 |
| INTERNATIONAL APPLICATION NO. PCT/US2003/030466 | | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/528,685 |
| INTERNATIONAL FILING DATE 25 September 2003 (25.09.2003) | | PRIORITY DATE CLAIMED 27 September 2002 (27.09.2002) |
| TITLE OF INVENTION METHODS AND COMPOSITIONS FOR TREATMENT OF NEUROLOGICAL DISORDER | | |
| APPLICANT(S) FOR DO/EO/US CHILDREN'S MEDICAL CENTER CORPORATION and BENOWITZ, Larry I. | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| <p>1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p style="margin-left: 20px;">c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> is attached hereto.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p style="margin-left: 20px;">c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p style="margin-left: 20px;">d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>Items 11 to 20 below concern document(s) or information included:</p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> | | |

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20. Other items or information:
Form 1449; References C1 - C12; Express Mail Cert. Label No. EV 653000732 US; Return Receipt Postcard.

| The following fees have been submitted | | | | CALCULATIONS | PTO USE ONLY |
|---|--------------------------|---|--------------|------------------------|--------------|
| 21. | <input type="checkbox"/> | Basic national fee (37 CFR 1.492(a))..... | \$300 | \$ | |
| 22. | <input type="checkbox"/> | Examination fee (37 CFR 1.492(c)) | | \$ | |
| If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... | | | | \$ | |
| All other situations..... | | | | | |
| 23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) | | | | | |
| If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... | | | | \$ | |
| Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... | | | | | |
| International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... | | | | | |
| All other situations..... | | | | | |
| TOTAL OF 21, 22 and 23 = | | | | 0.00 | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | | |
| - 100 = | /50 = | | x \$250 | \$ | 0.00 |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | | | \$ | 0.00 |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | \$ | |
| Total claims | - 20 = | | x \$ 50 | \$ | |
| Independent claims | - 3 = | | x \$200 | \$ | |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | | \$ | 0.00 |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ | 0.00 |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | | | \$ | 0.00 |
| SUBTOTAL = | | | | \$ | 0.00 |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | | | \$ | 0.00 |
| TOTAL NATIONAL FEE = | | | | \$ | 0.00 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | | | \$ | 0.00 |
| TOTAL FEES ENCLOSED = | | | | \$ | 0.00 |
| | | | | Amount to be refunded: | \$ |
| | | | | Amount to be charged | \$ |

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- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 50-0850 in the amount of \$ 0.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0850. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

David S. Resnick
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110-2131
US


SIGNATURE

David S. Resnick
NAME

34,235
REGISTRATION NUMBER

Practitioner's Docket No. 701039-52287

PATENT

IN THE UNITED STATES RECEIVING OFFICE

| International Application Number | International Filing Date | International Earliest Priority Date |
|----------------------------------|-------------------------------|--------------------------------------|
| PCT/US2003/030466 | 25 September 2003 25.09.03 | 27 September 2002 27.09.02 |

TITLE OF INVENTION: METHODS AND COMPOSITIONS FOR TREATMENT OF NEUROLOGICAL DISORDER
 APPLICANTS FOR DO/US: CHILDREN'S MEDICAL CENTER CORPORATION;
 BENOWITZ, Larry I.
 INVENTORS FOR DO/US: BENOWITZ, Larry I.
 U.S.S.N.: 10/528,685

VERIFIED CERTIFICATION OF EXPRESS MAILING DATE
 (INTERNATIONAL APPLICATION (37 C.F.R. section 1.10(c))

I declare that, on July 18, 2005 I deposited, with the United States Postal Service, in an envelope "Express Mail, Post Office to Addressee," bearing Label Number EV 653000732 US, addressed to the U.S. Receiving Office "MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450," and having an express mail certification that I executed, the following papers:

1. Transmittal Letter to the U.S. Receiving Office – PTO 1390 in duplicate (6 pp.);
2. Declaration/Power of Attorney – executed by L.I. Benowitz (3 pp.);
3. Supplemental Information Disclosure Statement (2 pp.);
4. Form PTO/SB08b (2 pp.);
5. References C1 – C12;
6. Return Receipt Postcard.

A copy of these papers from the file of this application is attached.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Date: July 18, 2005

Signature

Nicole M. Aguirre
 (type or print name of person certifying)